IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document relates to: *Konrad v. AbbVie Inc.*, No. 1:15-cv-00966 *Mitchell v. AbbVie Inc.*, No. 1:14-cv-09178	

PLAINTIFFS' PROFFER REGARDING THE CASE AGAINST ABBVIE FOR PUNITIVE LIABILITY

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May 27, 2017

INTRODUCTION

Evidence of AbbVie's failure to warn, negligent misrepresentation, and fraud is inextricably intertwined with that of its willful and wanton conduct. *See* Rough Transcript of Final Pre-Trial Conference, May 25, 2017, attached hereto as Exhibit 1, at 44-45, and 50. Indeed, "A punitive damages claim is not an independent cause of action or issue separate from the balance of a plaintiff's case. It is part and parcel of a liability determination …. Proof of gross, willful, wanton or malicious conduct by a defendant is not separate from proof of a defendant's negligence." *See Mason* v. *Texaco, Inc.*, 948 F.2d 1546, 1554 (10th Cir. 1991), *cert. denied*, 504 U.S. 910 (1992).

Liability bifurcation would be inefficient, unworkable, and cumulative. Much of the same evidence would have to be presented twice. There is simply no way to extract that which rose to the level of unreasonableness from that which rose to a higher degree of culpability, and to attempt to do so would unfairly prejudice Plaintiffs' case, keeping from the jury otherwise relevant evidence simply because that evidence also happens to show willful and wanton conduct.[1] Moreover, parsing liability proof is not warranted where it is the *totality* of it that tends to prove punitive liability. *See* Case Management Order No. 47, In re Testosterone Replacement Therapy Products Liability Litigation, No. 14 cv 1748 (N.D. Ill. May 8, 2017), ECF No. 1896 ("Taken together …" AbbVie's failure to warn and marketing could permit punitive verdict). Plaintiffs thus oppose any bifurcation of bellwether trials, and as set forth throughout, hereby proffer just some of the evidence that will prove willful and wanton conduct under Illinois law.

PROFFER OF PUNITIVE LIABILITY EVIDENCE

[1] By way of example, in *Konrad*, Tennessee's jury instructions for misrepresentation claims illustrate the unavoidable overlap. *See, e.g.*, T.P.I.—Civil 8.36 (Intentional Misrepresentation), 8.38 (Misrepresentation by Concealment), 8.39 (Nondisclosure of Known Facts), 8.43 (Negligent Misrepresentation), and 10.18 (Misrepresentation—Products).

As early as the late 1970s, literature in the scientific community showed a biologically plausible causal connection between testosterone and thrombus formation, vascular diseases, and atherosclerosis. *See* Case Management Order No. 47, In re Testosterone Replacement Therapy Products Liability Litigation, No. 14 cv 1748 (N.D. Ill. May 8, 2017), ECF No. 1896 at 27-28 (citing to Gerstman and Ardehali reports, which discuss early mechanism articles); Plaintiffs' Trial Exhibit 1166, attached hereto as Exhibit 2. Over the next two decades, the literature established the connection between testosterone and: estradiol, *see* Plaintiffs' Trial Exhibit 1331, attached hereto as Exhibit 3; CMO 47 at 27-28 (citing to Gerstman report, which discusses effects via estrogen); human platelet thromboxane A2 receptor density and aggregation, *see* Plaintiffs' Trial Exhibit 1038, attached hereto as Exhibit 4; and increases in hematocrit. *See* Plaintiffs' Trial Exhibit 1066, attached hereto as Exhibit 5. In the mid-1990s, as AbbVie developed AndroGel, its own clinical investigator brochure acknowledged certain adverse biological effects of testosterone, *see* Plaintiffs' Trial Exhibit 0438, attached hereto as Exhibit 6, at FST004610080, and the results of the clinical studies themselves began to signal the risks. *See* Plaintiffs' Trial Exhibit 0219, attached hereto as Exhibit 7, at 51-52.

In 2000, when FDA approved AndroGel for marketing and use in the United States, it did so with the limited indication of "hypogonadism." *See* Plaintiffs' Trial Exhibit 0511, attached hereto as Exhibit 8, at FST00429342. AbbVie immediately recognized the likely limited market for that indication and began aggressively to pursue market expansion, charting a course to grow the market from 150,000 men in 2000 to "3-4 Million Men" by 2001. *See* Plaintiffs' Trial Exhibit 0009, attached hereto as Exhibit 9, at 00109257. AbbVie's approach was to tout AndroGel for off-label uses and over-promote the drug's unproven benefits (*e.g.*, so-called "age-related" hypogonadism and "Low T"). *See* Plaintiffs' Trial Exhibit 0474, attached hereto as Exhibit 10, at 00605591. By 2002, the marketing campaign had taken shape to "motivate consumers to get tested

and seek treatment," *see* Plaintiffs' Trial Exhibit 0478, attached hereto as Exhibit 11, at FST17063589, and by 2003, the motto in the official AndroGel Business Plan was unabashed: "sell market expansion first and AndroGel second." *See* Plaintiffs' Trial Exhibit 0096, attached hereto as Exhibit 12. The 2004 AndroGel Business Plan reiterated a fundamental part of the expansion campaign: "Link hypogonadism to other chronic disease states." *See* Plaintiffs' Trial Exhibit 0519, attached hereto as Exhibit 13, at 00223483.

AbbVie's marketing knew no bounds, as it spent fifteen years influencing beliefs in the medical community and fears and desires in the aging male consumer. Starting in 2001, it had its hands in the creation of literature about "andropause" and the use of TRT to combat it. *See* Plaintiffs' Trial Exhibit 0483, attached hereto as Exhibit 14, Plaintiffs' Trial Exhibit 0485, attached hereto as Exhibit 15, Plaintiffs' Trial Exhibit 0486, attached hereto as Exhibit 16, at FST17095705, and Plaintiffs' Trial Exhibit 1079, attached hereto as Exhibit 17. It retained physicians as paid consultants whose role was to advocate in the medical community for those beliefs. *See, e.g.*, Plaintiffs' Trial Exhibit 0459, attached hereto as Exhibit 18, at FST10178543, and Plaintiffs' Trial Exhibit 0490, attached hereto as Exhibit 19. AbbVie formed "The AndroPause Task Force" to spread awareness. *See* Plaintiffs' Trial Exhibit 0488, attached hereto as Exhibit 20, at 00243529. AbbVie directly influenced the Endocrine Society, inserting its consultants to help formulate guidelines for TRT use in aging men. *See* Plaintiffs' Trial Exhibit 0537, attached hereto as Exhibit 21, at 00017048, Plaintiffs' Trial Exhibit 0538, attached hereto as Exhibit 22, at 00010019, Plaintiffs' Trial Exhibit 0539, attached hereto as Exhibit 23, and Plaintiffs' Trial Exhibit 0540, attached hereto as Exhibit 24, at 00033843. AbbVie marketed directly to consumers and physicians, spreading branded AndroGel messages and unbranded disease-state messages. *See, e.g.*, Plaintiffs' Trial Exhibit 0507, attached hereto as Exhibit 25, at FST06097916. The record is replete with examples of AbbVie's unbranded propaganda, from the IsItLow.com website to the

"shadow of your former self" campaign. *See* Plaintiffs' Trial Exhibit 0044, attached hereto as Exhibit 26. Over the years, FDA repeatedly put AbbVie on notice of the misleading nature of its claims for "age-associated" hypogonadism, *see*, *e.g.*, Plaintiffs' Trial Exhibit 0002, attached hereto as Exhibit 27, at FST00301153, but AbbVie's marketing never wavered.[2]

AbbVie knowingly pursued all of these strategies in the absence of studies showing efficacy and safety for the population to which it was marketing or long-term safety generally. Indeed, in 2004, FDA's Dr. Daniel Shames noted the absence of a defined condition for low testosterone in aging men and a dearth of adverse event data and clinical studies to support TRT's "widespread" use in that population. *See* Plaintiffs' Trial Exhibit 1020, attached hereto as Exhibit 28. That same year, a group of physicians, including some of AbbVie's own paid consultants, acknowledged that "[n]o studies to date have included a sufficient number of participants to adequately make [] assessments" about the "risk/benefit ratio" of TRT and called for a large study of 6,000 men to properly investigate. *See* Plaintiffs' Trial Exhibit 1092, attached hereto as Exhibit 29, Plaintiffs' Trial Exhibit 0571, attached hereto as Exhibit 30, at 0030997-998. AbbVie's own 2005 White Paper acknowledged a need to study "cardiovascular effects." *See* Plaintiffs' Trial Exhibit 0291, attached hereto as Exhibit 31, at 094116925.

Plaintiffs' expert, Dr. Hussein Ardehali, opines that there was evidence of a causal association between AndroGel and myocardial infarction (MI) and cerebrovascular accident (CVA) by as early as 2007.[3] *See* Ardehali Rpt., Appendix, attached hereto as Exhibit 32, at 8. And in late 2009, the Testosterone in Older Men (TOM) study was prematurely terminated due to

[2] AbbVie's 15-year marketing crusade is akin to the "insidious" marketing tactics of the defendant drug company that warranted a punitive verdict in *Proctor v. Davis*, 682 N.E.2d 1203, 1215-16 (Ill. 1997) (promoting off-label use and recruiting physicians to influence medical community).

[3] Similarly, Plaintiffs' expert hematologist, Dr. Henry Rinder, opines that adverse event reports, mechanistic data, and clinical trial data provided evidence of a causal association between AndroGel and VTE risk by as early as 2004. *See* Rinder Rpt., Appendix A, attached hereto as Exhibit 33, at 6.

an increased incidence of cardiovascular events in men using TRT in the study. *See* Plaintiffs' Trial Exhibit 1006, attached hereto as Exhibit 34. But neither suspicion of risk, risk signals, nor actual studies like TOM ever engendered any action on AbbVie's part. AbbVie never shifted its focus from sales to safety. It took no steps to warn physicians and undertook no large scale studies to investigate further. Instead, AbbVie's marketing crusade marched forward. And AndroGel labeling remained unchanged until 2015, when FDA *required* warnings as a result of *its own* review of literature and data. AbbVie's spring 2015 "Strategic Plan" explained succinctly why it had long avoided risk discussion and pushed money into marketing at the expense of research, lamenting FDA's new warnings as a "paradigm shift" that had caused a "dynamic change" in sales: "As a consequence, **the entire testosterone market has decelerated, with double digit declines** in the volume of both topicals and injectable TRTs." *See* Plaintiffs' Trial Exhibit 0142, attached hereto as Exhibit 35, at 13810816 (emphasis added). The warnings were too late for Plaintiffs Konrad and Mitchell.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 27, 2017, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Brendan Smith
Brendan Smith